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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/335,581	06/18/1999	JASON D. BANNAN	2016-4010US2	6638

7590 11/18/2003  
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NEW YORK, NY 10036

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/18/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n N .

09/335,581

Applicant(s)

BANNAN ET AL.29

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on th cover sheet with the corresp ndenc address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

#### **Office Action Vacated**

1. Applicant's request for vacating the last Office Action of February 12, 2003 is persuasive and therefore, that action is withdrawn.

#### ***Entry of Amendment***

2. Amendments filed on July 31, 2002 have been entered. Claims 50-55 have been amended. Claims 50-55 with respect to SEQ ID NO:34 **ONLY** are under consideration in this office action.
3. A complete reply to the final rejection must include cancellation of nonelected claims, claim language or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Drawings***

4. Figure 3 refers to sequences without sequence identifying numbers being described within the figure itself or the brief description of the drawings within the specification. Therefore, appropriate correction is requested.

#### ***Claim Objections***

5. Claims 51-54 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. All of the claims

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are drawn to a non-toxic, purified peptide consisting essentially of an amino acid sequence selected from the group consisting of SEQ ID NO:34. Thus, clarification is required to overcome the objection.

### ***Withdrawal of Rejections***

6. The following rejections have been withdrawn in view of applicants' amendments:

- a) the rejection of claim 55 under 35 U.S.C. 112, second paragraph;
- b) the rejection of claims 50-55 under 35 U.S.C. 101; and
- c) the rejection of claims 50-55 under the judicially created doctrine of obviousness-type double patenting; and
- d) the rejection of claims 50-55 under 35 U.S.C. 102(b).

### ***Response to Arguments***

7. Applicant's arguments filed July 31, 2002 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The new matter rejection of claims 50-55 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained in view of applicants amendments.

Applicants have amended the specification and claims to include the proviso that the peptide, SEQ ID NO:34 is not *Staphylococcal* enterotoxin B (SEB) or *Staphylococcal* enterotoxin C (SEC) or other native toxin.

Neither the specification nor originally presented claims provides support for the SEQ ID NO:34 peptide not being *Staphylococcal* enterotoxin B (SEB) or *Staphylococcal* enterotoxin C (SEC) or other native toxin. Applicant has not pointed to support in the specification for the negative limitation of peptide comprising SEQ ID NO:34. Furthermore, there is no support in the specification that teaches a peptide consisting of the amino acid sequence SEQ ID NO:34. Also, there is no support for a peptide, SEQ ID NO:34 being retained after dialysis to remove molecules with molecular weights of less than 6000-8000 daltons with the proviso that the larger molecule is not SEB or SEC or other native toxin. Applicant has pointed to support at pages 4 and 24 and figure 3 which show that SEB and SEC are identified as being known in the art for containing the 12-mer sequences. However Figure 3 makes no reference to SEQ ID NO:3, rather figure 3 is drawn to a comparison of other synthetic peptides having conserved regions from SEB and SEC. Moreover, neither do page 4 and 24 make reference to SEQ ID NO:34. At page 24 lines 18-19, the specification states that the preferred peptides of the invention are those that exclude full-length native toxin molecules, however the specification teaches the native toxins. The specification only provides for randomly cross-linked polymer peptides, and does not provide support for the specific sequence SEQ ID NO: 34. The genus described by consensus sequences does not inherently provide support for the addition of SEQ ID

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NO: 34. Therefore, the amended claims incorporate new matter and the rejection is maintained. rejected.

Applicants asserts that pages 23-24 lines 25-25 exemplifies a polymer peptide having SEQ ID NO:3 as having the capability of being removed by dialysis. However the exemplified peptide is cross-linked to a polymer wherein the polymer peptides are at least 6000 to 8000 daltons. The average size of the exemplified polymer peptides is about 12,000 to 15,000 daltons. The specification further states that small peptides may be removed using dialysis. However, the claims fail to recite cross-linking the peptide to create a peptide, consisting of SEQ ID NO:34 and a polymer that may or may not be removed. Applicants arguments go one to cite quotes which appear to create a sentence but in actually a fragments of sentences over the two pages. The claims fail to recite the cross-linked peptide polymers but rather extend the scope to include any large yet undefined molecule. Thus, applicants fail to show support for such a broad claim, therefore the new matter rejection is maintained.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is


703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers


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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 

October 31, 2003

  
MARK NAVARRO  
PRIMARY EXAMINER